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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,123	04/02/2002	Mary Collins	22058-514NATL	5639

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EXAMINER
DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
1647	8

DATE MAILED: 05/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,123	COLLINS ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, 19, 25-27, 34-37, drawn to isolated polynucleotide, polypeptide, host cell, process for producing a IL-13bc protein, pharmaceutical composition, method of identifying an inhibitor of IL-13 binding to receptor, fusion protein.

Group II, claim(s) 18, drawn to composition comprising antibody.

Group III, claim(s) 20, 21, drawn to pharmaceutical composition comprising inhibitor.

Group IV, claim(s) 22, drawn to method of inhibiting comprising administering an inhibitor.

Group V, claim(s) 23, 28-31, 39-37 drawn, in part, to method of administering protein and a method of treating an IL-13 condition or inhibiting the interaction of IL-13 with an IL-13 bc protein in a mammal comprising administering IL-13bc (antagonist) and a pharmaceutically acceptable carrier.

Group VI, claim(s) 32, 33, drawn to method for potentiating IL-13 activity comprising combining protein with IL-13 activity with protein and administering to subject.

Group VII, claim(s) 39-47, drawn, in part, to a method of treating an IL-13 related condition or inhibiting the interaction of IL-13 with an IL-13 bc protein in a mammal comprising administering an antibody to IL-13 or an IL-13-binding fragment thereof, and antibody to IL-13bc or an IL-13bc-binding fragment thereof, or an antibody to IL-13Rα1 or and IL-13Rα1-binding fragment thereof.

Group VIII, claim(s) 39-47, drawn, in part, to a method of treating an IL-13 related condition or inhibiting the interaction of IL-13 with an IL-13 bc protein in a mammal comprising administering an soluble form of IL-13Rα1 or IL-13R-binding mutants of IL-4.

Group IX, claim(s) 39-47, drawn, in part, to a method of treating an IL-13 related condition or inhibiting the interaction of IL-13 with an IL-13 bc protein in a mammal comprising administering a small molecule capable of inhibiting the interaction of IL-13 with IL-bc and a small molecule capable of inhibiting the interaction of IL-13 with IL-13Rα1.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups IV-IX do not share a special technical feature because the groups are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. A search and examination of all methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and/or the subject matter is divergent.

Groups I-III do not share a special technical feature because the groups are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The protein of Group I can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). The antibody of Group III can be used in materially different methods other than obtain the protein of Group I such as therapeutic methods. The product group III is structurally and functionally distinct from the product of groups I-II.

Inventions I/IV, VII-IX; II/IV-VI, VIII, IX and III/V-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions I/V, VI; II/VII and III/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can be used in a materially different process of using that product such as assays to identify other binding proteins. The product of Group II can be used as a probe in immunoassays or immunochromatography. The product of Group III can be used in assays to make antibodies.

Furthermore, PCT Rules only allows for the examination of the first product, the first method of making and using that product.

Claims 39-47 are generic to a plurality of disclosed patentably distinct species comprising antibody to IL-13 or an IL-13-binding fragment thereof, and antibody to IL-13bc or an IL-13bc-binding fragment thereof, or an antibody to IL-13Rα1 or and IL-13Rα1-binding fragment thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is required to select one polynucleotide sequence (SEQ ID NO:) and one polypeptide sequence (SEQ ID NO:). Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Amino acid sequences of different polypeptides are also structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to

represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Accordingly, only one (1) independent and distinct nucleotide/polypeptide sequence will be examined in a single application without restriction.

This is not a species election but a further election of a group. If Applicant will provide prior art references which disclose the other recited SEQ ID Nos, then these additional SEQ ID Nos will be rejoined to the elected invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

RMD
May 6, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER